REMARKS

This amendment is responsive to the Office Action mailed June 2, 2005 (hereinafter referred to as "the present Action"). Original claims 6-8 and 22-25 are under examination in the present action. All pending claims stand rejected.

Applicant has amended claim 6 to clarify the operation of the injection device in response to the present Action. Claims 9-21 are canceled. Claims 1-5 were previously canceled in response to a prior Action.

Support for the amendment of claim 6 is found throughout the specification, e.g., at page 2, lines 9-13; page 8, lines 1-7 and 18-20; page 9, lines 4-7; and Figs. 1-4. Applicant states that the amendment of claim 6 does not introduce new matter and that the aforementioned amendment does not require any change of inventorship pursuant to 37 C.F.R. §1.48(b). New claims 26 and 27 have been added. Support for new claims 26 and 27 is found throughout the specification particularly at page 2, line 27 to page 3, line 2; page 8 lines 1-2, 14-17 and 20-22; and Figs. 1-4.

Reconsideration of the instant Office Action, entry of the amendments submitted herewith and allowance of all pending claims are respectfully requested.

Finality of Office Action Premature

Applicant respectfully objects to the finality of the present Action. As noted by the Examiner on page 4 of the present Action, the rejection of claims 6-8 and 23-25 under 35 U.S.C. §103(a) for being "unpatentable over Tischlinger, 4,178,928, in view of Burroughs et al., 6,221,046" was a "new ground(s) of rejection." In addition, all prior grounds for rejection were deemed moot due to the new ground of rejection. As noted in MPEP §706.7(a), a "second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c)." Applicant respectfully submits that since the prior amendment did not "necessitate the new ground of rejection" and since no information disclosure statement was filed "during the period set forth in 37 CFR 1.97(c)," the finality of the present Action was premature. Applicant respectfully requests the withdrawal of the finality of the instant Action.

In an overabundance of caution, however, Applicant has filed with the foregoing Reply, a Request for Continued Examination pursuant to 37 C.F.R. §1.114(e). In the event that the Examiner does not rescind the finality of the present Action, Applicant requests the suspension of the present action. Applicant states that all requirements for the suspension of the present Action, i.e., prosecution closed on an application filed after June 8, 1995, filing of reply to the present Action and payment of the prescribed fee, have been satisfied.

35 U.S.C. §103(a)

Claims 6-8 and 22-24 were newly rejected as allegedly unpatentable over U.S. Patent No. 4,178,928 (Tischlinger) in view of U.S. Patent No. 6,221,046 (Burroughs). Applicant respectfully traverses this rejection because (i) the cited references fail to teach or suggest all of the currently claimed elements and (ii) the rejection has not identified a motivation or suggestion to modify prior art so as to arrive at the devices as currently claimed.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir.

1990). Applicant respectfully contends that neither reference cited by the Examiner "expressly or impliedly" suggest combining their teaching to produce the claimed injection device.

Applicant disagrees with the Examiner's assertion (at page 2) that Tischlinger "discloses the invention substantially as claimed." The device disclosed in claim 1 of Tischlinger patent (hereinafter referred to as "the Tischlinger device") is significantly different from the device of claims 6-8 and 23-27 of the instant application. In an effort solely to distinguish the injection device of the instant application from the Tischlinger device, Applicant has amended Claim 6 to emphasize the differences. For example, the present amendment further clarifies the functions of the septum plunger and protective sleeve. In particular, claim 6 has been amended to recite that the protective sleeve is moved into place to cover the needle after an injection when engaged by the septum plunger.

Unlike the currently claimed devices, the Tischlinger device does not include a septum plunger that is configured to isolate an injectable composition from the needle prior to pressing the plunger during injection and capable of moving the protective sleeve into place to cover the needle after an injection. The Examiner is of the incorrect opinion that the diaphragm (164) of the Tischlinger device is equivalent to the septum plunger of the device of the instant application. As discussed in column 3, lines 30 of the Tischlinger patent, the diaphragm (140) is "[a] flexible ... wall [that] extends across the rearward end of [the] cylindrical wall to provide the closing means for the forward end of the medicament chamber." According to the Tischlinger patent in column 4, lines 2-7, pressure from the medicament causes the "diaphragm cover" to "flex" so as to be engaged with "the pointed end of the spike" wherein the diaphragm cover is "pierced" by the spike to "allow the medicament to flow out." There is no suggestion in the Tischlinger patent that the diaphragm (164) is slidably arranged in the cartridge assembly or that it performs any other function other than to isolate the medicament from the forward end of the assembly.

Applicant specifically selected to refer to part (16) of the subject injection device as a "plunger" to denote its ability to move. As noted in Exhibit "A" attached to this Reply, the dictionary definition of a "plunger" is "a sliding piece driven by or against fluid pressure." As such, the amendment of claim 6 to recite that the septum plunger (16) is "slidably arranged within the housing" is unnecessary, however, in an effort to overcome the 103(a) rejection, Applicant made such an amendment.

In addition to the foregoing difference and further contrary to the Examiner's opinion, the Tischlinger device does not contain "a hollow needle having a distal end extending outside of the housing and having a proximal end extending longitudinally within the housing." The Examiner opines that the cannula (11) of the Tischlinger device is equivalent to the hollow needle (12) of the claimed device. As evidenced by Exhibit "B" attached to this Reply, a cannula is "a small tube for insertion into a body cavity." As discussed in the Abstract of the Tischlinger patent, "[a] nose piece is affixed to the ... end of the cartridge tube" which "mounts a cannula on its outside portion" and that when the diaphragm is "pierced by a spike" "fluid communication between the medicament chamber and the cannula" is established. It is clear from a careful reading of the Tischlinger patent that the cannula merely is a conduit for the medicament once the diaphragm is breached. Medicament is not retained in the cannula. As discussed on page 8, lines 19-25, the injection device of the instant application allows for the filling of the hollow needle prior to the needle penetrating the epidermis. This unique feature maintains the asepsis of the claimed injection device.

Applicant also refers the Examiner to Figs. 1-3 of the Tischlinger patent. [1] The Figures clearly indicate that the cannula of the Tischlinger device is exposed to the environment during use. As illustrated in Figs. 1-5 of the instant application, at no time during the use of the claimed injection device is the needle exposed to the environment. It is either covered by the sleeve prior to and after the injection or in the epidermis of the patient. Clearly, the Tischlinger device is akin to those "pre-filled administration devices" referred to in the Background of the Invention of the present application. "Such pre-loaded devices...have a number of drawbacks, including the inability to preserve the asepsis or sterility of the needle, as well as the general danger of using an exposed needle."[2] There is no suggestion in the Tischlinger patent that the shield (24) found in the Tischlinger device is capable of covering the needle after injection.

The Examiner cites U.S. Patent No. 6,221,046 (hereinafter referred to as "the Burroughs patent") for its teaching of a cap for an injection device. Applicant has amended claim 6 by

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[1] As stated in MPEP 804, 1, "those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent." Citing In re Vogel, 422 F.2d 438, 441-42, (CCPA 1970).

[2] In addition to the improvements of the claimed injection device over the prior art injection device, Applicant contends that the claimed device also reduces the likelihood of inadvertent needle pricks by health care workers whereas the Tischlinger device does not.

deleting "a removable cap" as a required element of the claimed device. Support for this amendment is found at page 10, lines 29-30. As such, the Burroughs patent is no longer relevant with respect to a determination of the patentability of the claimed injection device of claim 6. Assuming arguably that the Burroughs patent was relevant, it does not make up for the deficiencies of the Tischlinger patent with respect to the currently amended claims. Applicant submits that a person of skill in the art would not have been motivated to modify the Tischlinger device to (i) make the diaphragm slidable, (ii) to use the slidable diaphragm to engage the shield so that the cannula is covered after injection; (iii) to abandon the operative principle of using a spike to pierce the diaphragm thereby allowing the medicament to flow out of medicament chamber, past the spike and into cannula, and (iv) to replace the cannula with a hollow needle that can be filled prior to the injection after reading the Burroughs patent. As such, new claim 26, which is directed to the injection device of claim 6 with a protective cap, is clearly not obvious with respect to the Tischlinger patent in combination with the Burroughs patent.

In view of the current amendments, Applicant submits that the cited references do not establish a *prima facie* case of obviousness. As such, Applicant respectfully requests the reconsideration and withdrawal of the rejection of claims 6-8 and 22-25 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,178,928 in view of U.S. Patent No. 6,221,046.

CONCLUSION

Applicant respectfully submits that the claims are in a condition for allowance and notification to that effect is respectfully requested. Examiner Lam is invited to telephone the Applicant's attorney at (508) 478-0144 to facilitate prosecution of this application.

Please apply any charges or credits to Deposit Account No. 50-0590 referencing attorney docket number 023B.

Respectfully submitted,

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Alan F. Feeney
Attorney for Applicant
Reg. No. 43,609

IPSEN (BIOMEASURE)
27 Maple Street
Milford, MA 01757-3650
(508) 478-0144 telephone
(508) 478-2530 facsimile
alan.feeney@ipsen.com